

## REMARKS

Claims 1 and 37-95 are pending. Claims 2-36 are cancelled without prejudice or disclaimer. Claims 37-40, 42, 43, 47, 56, 72, 79, 80 and 81 are amended. No new matter has been added to the claims. Applicants respectfully request withdrawal of the rejections.

### ***Specification Objection:***

On page 2 of the Office Action, the Examiner has objected to instant disclosure and alleges that "the continuing data does not appear to be correct" and the "present application is continuation-in-part of patent application PCT/US99/16070." Applicants respectfully disagree with the Examiner and reiterate that the "application is a continuation of PCT/US99/16070, filed July 16, 1999". Applicants refer to the PCT/US99/16070 publication WO 01/05337 cover page and indicate that the application is a continuation-in-part of U.S. Serial No. 08/798,638, filed February 11, 1997, which is a continuation-in-part of U.S. Serial No. 08/726,313, filed October 2, 1996, which is a continuation-in-part of U.S. Serial No. 08/600,744, filed February 13, 1996, now U.S. Patent No. 5,869,400; however, the instant application is a "continuation" of PCT/US99/16070.

The Examiner also has alleged that the claims filed "do not have support from the specification" and directed to the claim objection set forth for a more complete explanation. Applicants state that claims are fully supported by the specification and refer to responses and arguments as set forth herein.

See for example, specification support for claimed terms, for example, "shell", "acetabular cup", and "femur cup" can be found in the specification (see for example, page 8, lines 24-26; page 9, lines 2-5; Figure 1; page 15, lines 8-12; and Figure 8). More specifically indicate that "shell" and "acetabular cup" are described, for example, on page 8, lines 24-26 and page 9, lines 2-5; and "femur cup" and "acetabular cup" are described, for example, on page 15, lines 8-12.

Support for claimed ranges, for example, for socket sizes can be found in the specification and original claims (see for example, page 17, lines 11-23; Table I:

Ranges for very small socket: 41 mm, small socket: 45 mm, and mid-size socket: 59 mm; and pages 26-28 for original claims 22-29).

In view of the clear support in the specification, withdrawal of the objection is earnestly requested.

***Claim Objections:***

On pages 2-3 of the Office Action, the Examiner has objected to claims 37-40, 42, 65-78, 80, 82-84, 89, 90, 92, 93, and 95 for various informalities. In response, applicants amend claims 37, 38-40, and 80 to correct the informalities, as suggested by the Examiner.

The Examiner also has objected to claims 42, 65-78, 89, 90, 92, 93, and 95 and alleged that the claims lack proper antecedent basis from the specification for using a "Three-cup prosthesis of shell, acetabular cup, and a femur cup." Applicants respectfully disagree with the Examiner. In response, applicants reiterate that the application is a continuation of the parent application PCT/US99/16070 and claims are supported by the specification (see for example, page 8, lines 24-26; page 9, lines 2-5; Figure 1; page 15, lines 8-12; and Figure 8). Applicants specifically indicate that "shell" and "acetabular cup" are described, for example, on page 8, lines 24-26 and page 9, lines 2-5; and "femur cup" and "acetabular cup" are described, for example, on page 15, lines 8-12.

Regarding claims 82-84, applicants again respectfully disagree with the Examiner and state that the claimed ranges are clearly supported by original specification (see for example, page 17, lines 11-23; Table I: Ranges for very small socket: 41 mm, small socket: 45 mm, and mid-size socket: 59 mm; and pages 26-28 for original claims 22-29).

Withdrawal of the objections is solicited.

***Claim Rejections:***

***Indefiniteness Rejections***

On pages 3-4 of the Office Action, the Examiner has rejected claims 37-41, 47, 56, 57-60, 64, 72, and 81-88 under various indefiniteness grounds. In response,

applicants amend claims 37-41, 43, 47, 56, and 72 for additional clarity and to obviate the rejections.

Regarding claims 37-41, to clarify the Examiners confusion, applicants clarify that the claims relate to "surface replacement", which does not require an artificial ball head. For additional description of a "surface replacement", applicants refer to the specification, for example, page 8, lines 34-35 to page 9, lines 1; Figure 8, (86), (90); and page 15, lines 8-12). For further clarity, applicants amend claim 37 (b) to read as "a femur cup that has a mating portion and defines a cavity to accommodate a femur head".

Regarding claims 81-88, applicants amend the independent claim 81 by addition pelvic socket size "of about 41 mm or more" to specify claimed dimensions. Amendment to the claim has support in the original specification (see for example, page 17, lines 11-23; Table I: Ranges for very small socket: 41 mm, small socket: 45 mm, and mid-size socket: 59 mm; and pages 26-28 for original claims 22-29).

Withdrawal of the rejections is respectfully requested.

#### **Obviousness Rejections**

On page 4 of the Office Action, the Examiner has rejected claims 1, 37, 38, 41, 42, 90, and 93 as allegedly being unpatentable over Graham *et al.* in view of McKellop *et al.* Applicants respectfully disagree, because at least the Office Action has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, at least two criteria must be met. First, there must be some motivation or suggestion to make the proposed combination or modification of the references. Further, "the teaching or suggestion to make the claimed combination must be found in the prior art, and not based on the applicant's disclosure." MPEP 2142, discussing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, the combined, or modified, references must teach or suggest all claim limitations.

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there

is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). See *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants submit that the rejections do not meet this test.

Applicants provide following arguments to overcome the 35 USC § 103 rejections:

***Graham does not teach the femur cup that can accommodate a femur head of 35 mm or greater***

The Examiner has misunderstood Graham disclosure of the "shell (13)" and interpreted that the shell "corresponds to the acetabular cup as claimed [ ] which can be 2.0 or 3.5 mm thick which corresponds to the femur cup as claimed". Applicants point out that Graham does not describe a femur cup that can accommodate a femur head of a cross-section greater than about 35 mm, as disclosed in the instant invention. Applicants point out that until the instant invention, conventional cups were limited to 22-32 mm in diameter. Similarly, the Graham disclosure does not teach a femur cup of a diameter larger than 32 mm. Applicants also note that highly cross-linked UHMWPE material of the instant invention, having reduced elastic modulus and reduced contact stress, among other things, made it possible to reduce thickness of the polyethylene cup in order to obtain larger femoral cup as claimed. Graham did not provide any motivation to cross-link UHMWPE material in order obtain the femur cup of the instant invention.

***Graham uses conventional UHMWPE***

Graham uses conventional UHMWPE to make polymeric cups (See col. 4, lines 61-64). In contrast, the instant invention uses cross-linked UHMWPE polymer (See for example, specification page 3, lines 11-15). While Graham describes various mechanical modification of polymeric cups to improve wear resistance (see for example, col. 3, lines 1-13 and lines 53-97 to col. 4, lines 1-2), it does not provide any teaching to improve chemical/mechanical properties, such as cross-linking by irradiation in combination with melting.

***Combination on all segments of Graham (20) does not provide the prosthesis of instant claim 42***

With regard to claim 42, applicants indicate that the Examiner misapprehends "cup (18) of Graham and the femur cup." Applicants also point out that Graham does not disclose a contact between polyethylene and the metal femoral head, and thus Graham specifically teaches away by having an articular contact between the metal head and ceramic (See col 5, lines 4-9; Fig. 1 (20)). In contrast, claim 42 describes "a metallic acetabulum shell, wherein the shell can be fixed to the pelvis to be disposed to be in contact with an acetabular cup." Therefore, the femur cup according to the instant claim 42 is not met by combination of all segments (20) of Graham.

***McKellop in combination with Graham does not make instant invention obvious***

Applicants refer to the arguments made above regarding Graham *et al.* disclosure and state that McKellop *et al.* do not rectify deficiencies of Graham for the reasons set forth below.

***Although McKellop teaches cross-linked UHMWPE, there is no disclosure supporting a cup that can accommodate a head of 35 mm or greater***

On page 4 of the Office Action, the Examiner has referred to the front page and col 2, lines 12-18 of McKellop and alleged that McKellop "teaches that it was known to cross-link similar prosthetic cups" of the instant invention. Applicants disagree with the Examiner and indicate that McKellop's invention does not apply to cups of the instant invention and refers to conventional cups. Applicants refer to McKellop disclosure at col 4, lines 20 to 28, regarding the gamma radiation or e-beam radiation produced UHMWPE of "comparable low wear rates (WO98/01085)" and point out that the disclosure does not refer to wear behavior of femoral heads larger than 32 mm.

Skilled artisans at the time would have no motivation to apply McKellop to come up with the cups of the instant invention. A femur cup larger than 32 mm in diameter cannot possibly be used unless a thinner layer of "wear resistant-polymer" is used (See for example, specification page 2, lines 4-26), which was not undertaken until the instant invention (See for example, specification page 15, lines 21-29).

***Instant invention has satisfied a long-felt but previously unmet need***

Applicants note that throughout the history of total hip replacement, from its very inception in 1959, the experience with all plastic materials that were tried for total hip replacement surgery including polytetrafluoroethylene, ultra high molecular weight polyethylene, delrin and others, a single dominant issue existed which was the major influence on the wear of the plastic. That single issue was head size. Small femoral heads wore less, large femoral heads wore more (see for example, Nakajima I., *Nippon Seikeigeka Gakkai Zasshi*. 1979, 53(8):919-36; Elfick *et al. J Arthroplasty*. 1998, 13(3):291-5) (Abstracts of the references are enclosed).

Early attempts at hip replacement tried large head sizes; however, results indicated higher volumetric wear rate increased with respect to size of femoral head, for example, 32 mm diameter femoral head components (Nakajima I., *Nippon Seikeigeka Gakkai Zasshi*. 1979, 53(8):919-36; Livermore *et al., J Bone Joint Surg Am*. 1990, 72(4):518-28; Clarke *et al. Proc Inst Mech Eng [H]*. 1997, 211(1):25-36; Hirakawa *et al. J Biomed Mater Res*. 1997, 36(4):529-35; Elfick *et al. J Arthroplasty*. 1998, 13(3):291-5) (Abstracts of the references are enclosed). In response, the field went to smaller head sizes (Affatato *et al. Chir Organi Mov*. 1997, 82(4):393-9) (Abstract of the reference is enclosed).

Even when started using ultra high molecular weight polyethylene in 1962, the same issue existed and skilled artisans continued to use and recommend smaller head size, for example, less than 32 mm in diameter. Because a large head diameter could not be utilized, investigators alternatively optimized head-neck diameter ratio in an attempt to enhance range of motion (Chandler *et al. Clin Orthop*. 1982, (166):284-91) (Abstract of the reference is enclosed).

However, even the 32 mm head size fell into disfavor as increasing evidence made clear the fact that the 32 mm head size had a higher volumetric wear rate, a higher incidence of periprosthetic osteolysis and an increased the risk of dislocation (Kelley *et al. Clin Orthop*. 1998, (355):163-70; Elfick *et al. J Arthroplasty*. 1998, 13(3):291-5) (Abstracts of the references are enclosed). Accordingly, the field continued to avoid larger heads (Manley *et al. J Bone Joint Surg Am*. 1998, 80(8):1175-85; Affatato *et al. Chir Organi Mov*. 1997, 82(4):393-9) (Abstracts of the references are enclosed).

The instant invention has solved a long-felt but previously unmet need by providing thinner and wear-resistant polymer cups (See for example, specification page 2 lines 4-26), which made it possible to make polymeric cups that accommodate femur heads of 35 mm or greater while minimizing wear.

Large head femur presents various advantages, including improved range of motion, reduced likelihood of dislocation, and extended lifetime of the prosthesis (see specification, for example, page 3, lines 20-25).

The existence of this long-felt but previously unmet need and the failure of others constitutes further evidence of the patentability of the present invention. See *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) (MPEP 716.04, Rev. 1, Feb. 2003).

***McKellop disclosure does not provide a femur head of 35 mm or greater***

McKellop disclosure contains no mention of femoral head diameter. Specifically, there is no mention of using femoral head diameters larger than 32 mm. Clearly, McKellop *et al.* did not disclose that this material would have a unique relationship to femoral head diameter nor that specifically the relationship of head size to wear would be the exact opposite of the entire world's experience with this polymer and many others over the previous four decades. Applicants further state that in order to accommodate a head of 35 mm or greater, it is necessary to minimize cup thickness (See for example, specification page 2, lines 4-26; page 15, lines 8-29; page 16, line 7 through page 7, line 23). McKellop, however, does not address thickness in relation to head diameter.

***Townley in combination with McKellop does not make the instant invention obvious***

On pages 5-6 of the Office Action, the Examiner rejected claims 1, 37-41, 43-59, 61-62, 64-89, 91, 92, 94, and 95 as allegedly being unpatentable over Townley *et al.* in view of McKellop *et al.* Applicants respectfully disagree with the Examiner. Applicants refer to the arguments made above regarding McKellop *et al.* disclosure and state that Townley *et al.* do not rectify deficiencies of McKellop. Therefore, combination of

McKellop and Townley *et al.* does not make the instant invention obvious. Withdrawal thereof is respectfully requested.

The Examiner alleged that the applicants "have not disclosed that the cup thickness provides some advantages". In response applicants point out that the specification clearly discloses advantages of minimized cup thickness (see for example, page 3, lines 20-25). The Examiner also alleged that the applicants "have not disclosed that the 70 mm to 90 mm diameter ball provides some advantages". In response applicants point out that the specification clearly discloses advantages of larger socket diameter, included head diameters 40 or more (see for example, page 3, lines 25-34 to page 4, lines 1-7). As mentioned earlier, specific examples of the advantages of larger head include, improved the range of motion, reduced the likelihood of dislocation, and extended lifetime of the prosthesis.

***McKellop and Townley in combination with DeCarlo, Jr., or Teinturier do not make instant invention obvious***

On page 7 of the Office Action, the Examiner has rejected claims 60 and 63 as allegedly being unpatentable over Townley and McKellop as applied to claim 1 and further in view of DeCarlo, Jr., or Teinturier. Applicants refer to the arguments made above regarding Townley *et al.* and McKellop *et al.* disclosures and state that DeCarlo, Jr., or Teinturier do not rectify deficiencies of Townley *et al.* and McKellop *et al.* DeCarlo describes cups with greater degrees of freedom and Teinturier discloses contact surfaces for ovoid heads. However, DeCarlo, Jr., or Teinturier does not teach nor provide any motivation to obtain irradiated wear resistant polymeric cups that can accommodate heads of 35 mm or greater. Because, there was no teaching until the instant invention that a femur cup larger than 32 mm in diameter cannot possibly be used unless a thinner layer of "wear resistant-polymer" is available. Therefore, combination of Townley *et al.* and McKellop *et al.* and DeCarlo, Jr. *et al.*, or Teinturier *et al.* does not make the instant invention obvious.

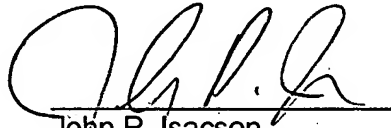
Withdrawal of the rejections is solicited.



### CONCLUSION

In view of this Amendment and Applicants' remarks above, Applicants respectfully submit that claims 1 and 37-95 are allowable. If any additional fees or additional extensions of time are required with the filing of this Amendment, Applicants respectfully request such fees and extensions be charged to Deposit Account No. 08-1641. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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